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# INVENTORY OF EXISTING SAFETY GUIDELINES IN BIOTECHNOLOGY

## MONOGRAPH

Information transmitted by the Government of the Russian Federation

SUMMARY

1. In Russia genetic engineering is regulated by law in accordance with the current sanitary and anti-epidemic guidelines and the "provisional regulations on safety of work with recombinant deoxyribonucleic acid (DNA)" drawn up in 1988 by the Interdepartmental Commission of the Presidium of the Russian Academy of Sciences.

2. There is now a need for a revision of the existing rules and the establishment of a modern framework of laws and standards to regulate the development of biotechnology and genetic engineering in Russia. This view is that of the scientific community, as expressed at the first All-Russian Congress on Biotechnology (Moscow, 1992), and it is shared by the Government.

3. The present need to establish a framework of laws and standards for biotechnology in Russia is dictated by such social and economic factors as the following:

The intense development of bioengineering in Russian scientific centres;

The growing range of genetically modified organisms (GMOs) that have been produced (genetically modified micro-organisms, plants and animals);

The development of biotechnological products for medical and agro-industrial application and steps to launch them on the international market;

The start of field testing of genetically modified organisms;

The growing involvement of joint ventures and commercial enterprises in GMO development and testing activities (field trials, clinical trials, etc.) that require Government supervision;

The expansion of international cooperation in the field of genetic engineering and biotechnology, which in each case require regulation by law.

4. The institution of a framework of laws and standards in the field of biotechnology presupposes the adoption, in a first phase, of three fundamental measures:

(a) The drafting of a law on genetic engineering;

(b) The drafting of rules relating to safety of work in genetic engineering;

(c) The devising of machinery for the implementation in Russia of a law on genetic engineering and of the corresponding safety regulations.

5. Accordingly, in the summer of 1993 an interdepartmental coordinating commission on legal regulations of work in the sphere of genetic engineering was set up, associating the Ministry of Science and Technology, the Ministry for the Protection of the Environment and Natural Resources and the Presidium of the Russian Academy of Sciences.

6. In conformity with its mandate from the Government of the Russian Federation the Coordinating Commission prepared a bill on genetic engineering, which in January 1994 was transmitted to the Government of the Russian Federation for consideration and subsequent submission to the State Duma. The aim of the law is to regulate social relations in the field of genetic engineering; to lay down a legal basis for formulating and implementing State policy in this sphere; to protect human health and to safeguard the environment from the potentially harmful consequences of the use of GMOs and GMO products; to establish legal limits on the introduction of GMOs into the ecosystem; to prevent uncontrolled use of the latest biotechnologies; to establish conditions permitting the full use of the fruits of the latest biotechnologies for the benefit of the national economy and social aspirations; to regulate international relations.

7. The bill comprises 5 sections, made up of 24 articles: I - general regulations, II - safety in genetic engineering, III - the organization of work in genetic engineering; IV - responsibility in genetic engineering; V - international cooperation in genetic engineering. It is intended that the law will extend to such aspects of genetic engineering as basic research, the design and experimental and industrial production of GMOs and/or GMO products, and the deliberate introduction of GMOs into the ecosystem to improve agriculture and other processes of importance to the national economy.

8. The principal burden of direct regulation of relations in this sphere falls upon the safety regulations for the conduct of genetic engineering, while the law itself is basically intended to serve as a fundamental frame of reference.

9. The system of legal regulation developed within the framework of the law on genetic engineering:

Ensures optimum conditions for the development of genetic engineering in Russia;

Guarantees the necessary appraisal of the potential risk involved in genetic engineering and observance of the corresponding safety measures;

Prevents the uncontrolled introduction of recombinant products for different types of application, and the unplanned release into the environment of GMOs (as a result of possible accidental leakages in laboratories or in bioreactors, or in the course of field experiments);

Provides a mechanism for integrating Russia into the international system of legal regulation of biotechnology.

10. The contents of the proposed bill on genetic engineering fully correspond to the range of foreign legislation and if necessary could be included in the European system for the regulation of genetic engineering.

LIST OF DOCUMENTS TRANSMITTED TO THE SECRETARIAT AND AVAILABLE FOR CONSULTATION ON REQUEST:

None.

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